K091154

Nucletron

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MAY 18 2009

Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	8671 Robert Fulton Drive Columbia, MD 21046
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Elaina Colby Manager Quality Assurance & Regulatory Affairs

New Device Name:

Trade/Proprietary Name:	Interstitial Ring CT/MR Applicator Set & Utrecht Interstitial Fletcher CT/MR Applicator Set
Common/Usual Name:	Gynecological Brachytherapy applicator
Classification Name:	Remote controlled radionuclide applicator system accessory
Classification:	21Cfr892.5700 Class II

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Ring CT/MR Applicator Set and Standard CT/MR Applicator set	k983341

Description:

The Interstitial Ring CT/MR Applicator Set is based on the Ring CT/MR Applicator Set enhanced with the addition of nine guiding holes in the ring tube (seven holes for part number 110.130). These guide holes allow placement of guiding tubes through which Proguide needles (k060349) can be inserted into the tumor. The addition of interstitial needles makes it possible to achieve asymmetric alteration of the dose distribution. The needles are inserted

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perpendicular to the ring and are parallel to the tandem. The applicator is fully CT/MR compatible. The device is composed of polymers, to eliminate distortion on CT or MR imaging. Interstitial needles can be used for treatment of carcinoma where no lumen or cavity is available.
The device is similar to the legally marketed predicate device Vienna Ring CT/MR Applicator Set. The difference between this device and the Vienna Ring CT/MR Applicator Set is that this device allows the use of Proguide needles instead of the titanium needles used with the Vienna Ring CT/MR Applicator Set

The Utrecht Interstitial Fletcher CT/MR Applicator Set is based on the legally marketed predicate device Standard CT/MR Applicator Set enhanced with five similar guiding holes in each ovoid as the guiding holes in the ring of the Interstitial Ring CT/MR Applicator Set. These guiding holes allow placement of guiding tubes through which Proguide needles (k060349) can be inserted into the tumor. The addition of interstitial needles makes it possible to achieve asymmetric alteration of the dose distribution. The needles are inserted perpendicular to the ovoids. The applicator is fully CT/MR compatible. The device is composed of polymers, to eliminate distortion on CT or MR imaging. Interstitial needles can be used for treatment of carcinoma where no lumen or cavity is available.

The MR line markers are optional devices that can make the channels of the Nucletron CT/MR applicators visible using magnetic resonance imaging. The markers consist of a thin Teflon tube that can be filled with an appropriate fluid that is clearly visible on magnetic resonance images.
The tubes are inserted before imaging in the channels of the CT-MR applicator and are removed before the treatment of the patient.

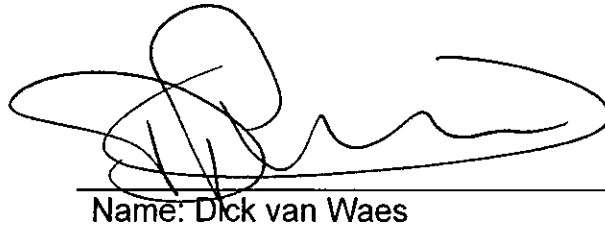
The devices are used as accessories to the Nucletron microSelectron Afterloaders

Intended use:

The intended use of the device is gynecological brachytherapy procedures for cancer treatment of the cervix and endometrium. Optional needles can be placed for interstitial brachytherapy.

Summary of technological considerations:

The Interstitial Ring CT/MR Applicator Set and the Utrecht Interstitial Fletcher CT/MR Applicator Set are substantially equivalent to the cleared predicate devices, Ring CT/MR Applicator Set and Standard CT/MR Applicator set, k983341



09-04-2009

Name: Dick van Waes
Title: Business Manager
Nucletron B.V.
Veenendaal, The Netherlands

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2009

Ms. Elaina M. Colby
Manager, Regulatory Affairs
Nucletron Corporation
8671 Robert Fulton Drive
COLUMBIA MD 21046-2133

Re: K091154
Trade/Device Name: Interstitial Ring CT/MR Applicator Set & Utrecht Interstitial Fletcher CT/MR Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: April 20, 2009
Received: April 21, 2009

Dear Ms. Colby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K091154

Device Name: Interstitial Ring CT/MR Applicator Set &
Utrecht Interstitial Fletcher CT/MR Applicator Set

Indications for Use: The intended use of the device is gynecological brachytherapy procedures for cancer treatment of the cervix and endometrium. Optional needles can be placed for interstitial brachytherapy..

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 subpart D) (Part 21 CFR 801 subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091154